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Subject: Comments on the HPV test plan for Dechlorane Plus

The following comments on OxyChem's test plan for the chemical Dechlorane Plus are submitted on behalf of the Physicians Committee for Responsible Medicine, People for the Ethical Treatment of Animals, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than ten million Americans.

Occidental Chemical Corporation submitted its test plan on September 24, 2004, for 1,2,3,4,7,8,9,10,13,13,14,14-dodecachloro-1,4,4a,5,6,6a,7,10,10a,11,12,12a-dodecahydroy-1,4:7,10-dimethanodibenzo[a,e]cyclooctene (CAS No. 13560-89-9), referred to as Dechlorane Plus. This chemical is a flame retardant that is incorporated into polymer systems, which are then used to coat electrical wires, cables, and computer connectors. OxyChem compiled a substantial amount of existing data on Dechlorane Plus to fulfill almost all SIDS endpoints for physiochemical properties, environmental fate, ecotoxicity, and mammalian toxicity. We commend the thoroughness of this submission and support the weight-of-evidence approach taken by OxyChem to meet the SIDS endpoint for acute toxicity to fish. On page 9 of the test plan, OxyChem states, " the two acute fish toxicity studies are inadequate by themselves...however, there were three bioaccumulation studies, which lasted up to 30 days with the same species of fish and which resulted in no mortality to those fish. Consequently, the acute toxicity to fish endpoint is considered fulfilled by the corroborative data." This is a thoughtful and scientifically valid analysis of the toxicity of Dechlorane Plus. Furthermore, the EPA has stated that acute fish tests are inappropriate for compounds with log $K_{o/w}$ values above 4.2. Analysis of fish toxicity for an insoluble chemical such as Dechlorane Plus, which has a log $K_{o/w}$ value of 9.3, is not warranted.

At this time, however, we question OxyChem's proposal to conduct a combined reproduction/developmental screen, OEDC 421, which would result in the death of at least 675 animals.

Although there are no available data on reproductive and developmental toxicity of Dechlorane Plus *per se*, it is premature to propose testing before reviewing all existing data for this chemical, as well as data for analogous chemicals. For example, three

repeated dose studies with Dechlorane Plus were conducted with rats and rabbits with no histopathological effects on any organs, including those analyzed in the 90-day repeated dose study. In the robust summaries (p. 39), OxyChem states that "approximately 30 tissues and organs were collected for histopathological examination." If the company is able to provide a list of the reproductive organs examined by histopathology, it may be able to satisfy the SIDS endpoint for reproductive toxicity.

We are also concerned that little attempt has been made to bridge the data gaps for reproductive and developmental toxicity with existing data from similar or analogous chemicals. We would like to know if OxyChem has reviewed toxicity data for the chlorinated paraffins class of chemicals. These compounds have approximately the same chain length and percentage of chlorination as Dechlorane Plus. Studies on reproductive toxicity were conducted in pregnant rats and rabbits with the chlorinated paraffin C14-17, 52% chlorine, with no indications of teratogenic effects. Elevated absorption and abortion rates were observed in rabbits at maternally toxic levels only (Anonymous, 1992). We strongly urge OxyChem to review these studies in order to eliminate additional animal tests. These data may be sufficient to satisfy the SIDS endpoints for reproductive and developmental toxicity for Dechlorane Plus, once their relationship to the sponsored chemical is explained.

OxyChem has also proposed additional genotoxicity testing but does not specify whether they intend to conduct these studies *in vivo* or *in vitro*. We do not believe additional testing for this endpoint is required for a screening level program such as HPV. Dechlorane Plus was non-mutagenic in two Ames tests and was not cytotoxic in the mouse lymphoma assay. Moreover, micronucleus tests with chlorinated paraffins, including C14-17, 52% chlorine, did not detect any increased incidence of micronuclei-containing polychromatic erythrocytes. The authors of the study conclude that the preponderantly negative results of studies on genotoxicity suggest a non-genotoxic mechanism of tumorigenic action (Anonymous, 1992). We ask that OxyChem first review these data as they may be used to satisfy the endpoint for genetic toxicity. No authority requires *in vivo* genetic toxicity testing following negative *in vitro* results. EPA guidance specifically encourages HPV participants to use *in vitro* genetic toxicity testing to generate any needed genetic toxicity screening data, unless known chemical properties preclude its use (Wayland, 1999; *Federal Register*, 2000).

Thank you for your attention to these comments. I may be reached at 202-686-2210, ext. 327, or via e-mail at *meven@pcrm.org*.

Sincerely,

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References

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